IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GUARDANT HEALTH, INC., Plaintiff and Counterclaim-Defendant, v. TEMPUS AI, INC., Defendant and Counterclaim-Plaintiff.	)	C.A. No. 25-82-RGA **JURY TRIAL DEMANDED**

TEMPUS AI, INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO COMPLAINT AND COUNTERCLAIMS AGAINST GUARDANT HEALTH, INC.

Defendant Tempus AI, Inc., by and through its undersigned counsel, hereby files its Answer and Affirmative Defenses to Plaintiff Guardant Health, Inc.'s Complaint (D.I. 1), along with its Counterclaims. Because Tempus is the true plaintiff in this action, alleging, among other things, that Guardant has engaged in a campaign of false and misleading advertising, Tempus first sets forth its counterclaims, which state the full scope of the misconduct Tempus alleges, followed by its Answer to Guardant's action for declaratory judgment, which addresses those same allegations.

COUNTERCLAIMS

1. Guardant launched a false advertising campaign that misleads oncologists who use Tempus's products to guide treatment decisions for cancer patients. Guardant's ads make false and misleading comparisons between Tempus's and Guardant's products to suggest that Guardant's products are superior when they are not. Guardant's acts are intentional, and part of a coordinated, ongoing, and multi-faceted campaign to harm Tempus. Accordingly, Tempus brings these

counterclaims to put a stop to Guardant's unlawful activities, protect its customers from misinformation, and obtain redress for the harms caused by Guardant's actions.

INTRODUCTION

2. Founded in 2011, Guardant was an early leader in the liquid biopsy cancer diagnostics field and, for a time, a darling of the biotech finance world. In recent years, however, Guardant has confronted stiffening competition, declining market share for its core liquid biopsy products, and significant cash burn as it struggles to turn a profit while carrying more than $1 billion in debt.

3. Tempus, founded in 2015, is one of Guardant's primary competitors. Within just a few years of its founding, Tempus both erased Guardant's considerable head start in oncology testing and developed a diversified platform extending beyond traditional diagnostic testing products. This diversified platform provides Tempus with multiple revenue streams compared to Guardant, and has attracted significant interest from healthcare investors, including one of Guardant's most prominent early backers.

4. By 2024, Guardant had squandered pole position in its core testing business, failed to build a competitive diversified platform or products beyond liquid biopsy testing, lost important investors to Tempus, and accumulated some $1 billion in debt, having never turned a profit in its 13-year existence. Guardant was desperate to reverse its fortunes. As desperate companies sometimes do, it resorted to unlawful tactics to attack its most threatening competitor.

5. While Guardant's attacks against Tempus began in early 2024, Guardant recently launched an advertising campaign that makes false and misleading comparisons between the companies' liquid biopsy tests. This conduct has serious consequences because of its potential impact on oncologists and the patients they treat.

6. Guardant's false advertising campaign is willful and its motive transparent, especially in view of its declining market share, other actions Guardant has taken to target Tempus, and, most significantly, the stances Guardant previously took on the dangers of comparative advertising in the diagnostic testing industry.

7. Before targeting Tempus, Guardant twice sued other competitors for false advertising based on head-to-head product comparisons like those at issue here. In a lawsuit filed in 2021, Guardant took the position that comparisons between diagnostic tests "necessarily" create "a misleading apples-to-oranges result that cannot legitimately be used to claim that one test is superior to the other." In Guardant's own words, these apples-to-oranges comparisons are dangerous because "[t]hey give the false impression that one is superior to the other, and have more to do with what they conceal than the quality of the products."

8. Given the misleading nature of comparative advertising of diagnostic tests, Guardant's co-CEO, Helmy Eltoukhy, testified in November 2024 that Guardant's advertising policy is to "take sort of the high road" and "just talk about the merits of [Guardant's] own products"—and specifically not to "engage in comparative advertising against its competitors." Eltoukhy's testimony was central to Guardant's obtaining a substantial verdict against another competitor that Guardant alleged had engaged in the very type of advertising that Guardant has now deployed against Tempus.

9. But what Guardant was saying in court contradicted what it was doing in practice. Less than a month after Eltoukhy claimed that Guardant was taking the "high road" and not engaging in comparative advertising, Tempus learned that Guardant was doing exactly that: disseminating false ads comparing Guardant's tests to Tempus's. Guardant's false advertising campaign has already caused considerable confusion among the doctors who rely on Tempus's

tests and has resulted in Guardant wrongly acquiring business from doctors who had previously relied on Tempus's tests.

10. While Guardant's actions show that its false and misleading ads were designed to and did harm Tempus, the other, more serious, victims of Guardant's unlawful conduct are the cancer patients whose care has been undermined because of the misinformation Guardant has spread about Tempus, its products, and their performance. Tempus files these Counterclaims to protect itself and the doctors and patients it serves.

COUNTERCLAIM PARTIES

I. Guardant Health, Inc.

11. Guardant is a corporation organized and existing under Delaware law with its principal place of business at 3100 Hanover Street, Palo Alto, CA 94034.

12. Guardant was founded by Helmy Eltoukhy and AmirAli Talasaz in 2011. Prior to founding Guardant, Eltoukhy and Talasaz worked together at Illumina, Inc., which manufactures genomic-sequencing machines and competes with Guardant in the commercial liquid biopsy space.

13. Guardant markets and sells commercial cancer screening tests to clinical and biopharmaceutical customers. Approximately 90% of Guardant's 2023 revenue came from precision oncology testing. Guardant focuses on liquid biopsy tests, which use samples drawn from a patient's blood to detect and diagnose cancer.

II. Tempus AI, Inc.

14. Tempus is a corporation organized and existing under Delaware law with its principal place of business at 600 West Chicago Avenue, Chicago, IL 60654.

15. Tempus is a healthcare technology company advancing precision medicine through the practical application of artificial intelligence. It was founded in 2015 by Eric Lefkofsky after

his wife was diagnosed with breast cancer. Mr. Lefkofsky realized at the time that the many recent advances in data and technology were not being optimized to find treatment options for cancer patients. Mr. Lefkofsky sought to harness the power of data analytics and AI to improve patient care.

16. In the years since its founding, Tempus has combined next-generation sequencing ("NGS") tests, real-world data, and artificial intelligence to enhance the diagnosis and treatment of cancer and other major diseases.

17. To accomplish these goals, Tempus has developed a broad portfolio of tools designed to transform healthcare data into actionable insights for physicians, patients, researchers, and life-sciences companies. Tempus operates certified clinical laboratories in Chicago, Illinois; Atlanta, Georgia; Durham, North Carolina; and Aliso Viejo, California.

18. Tempus's business is organized under three general product lines: Genomics, Data and Services, and AI Applications. Each is designed to enable and enhance the others to the benefit of patients and doctors.

19. Like Guardant, Tempus offers diagnostic tests in the liquid biopsy market. Unlike Guardant, Tempus's diagnostic test menu is broad and offers physicians a single comprehensive platform for oncology tests, including solid tumor testing, hereditary testing, minimal residual disease testing and monitoring, and algorithmic testing, transforming the way cancer is diagnosed and treated.

JURISDICTION AND VENUE

20. The United States District Court for the District of Delaware has original jurisdiction over this case under 28 U.S.C. § 1331 and 15 U.S.C. § 1121 because Tempus's claims arise under the Lanham Act. This Court has supplemental jurisdiction over Tempus's state-law claims under 28 U.S.C. § 1367.

21. This Court has personal jurisdiction over Guardant because Guardant has submitted itself to this Court's personal jurisdiction by filing its Complaint. Additionally, Guardant is subject to personal jurisdiction because it is a Delaware corporation and resides in this District.

22. Venue is proper in this District under 28 U.S.C. § 1391(b)(1) because Guardant resides in Delaware and is subject to personal jurisdiction in Delaware.

FACTUAL BACKGROUND

I. Guardant Seeks to Harm Tempus as It Stumbles in the Marketplace

23. Although Guardant began as the dominant player in the liquid biopsy space, its fortunes have declined in recent years as Tempus has grown and substantially cut into Guardant's market share. Guardant has substantial economic incentive to reverse that decline. Unable to do so through better or more attractive product offerings, Guardant set its sights on harming Tempus. Its actions against Tempus throughout 2024 reflect this intent. Guardant transparently sought to disrupt Tempus's IPO, spread false statements to investors about Tempus, induced Tempus's employees to violate non-solicitation clauses in contracts, and, finally, launched a false advertising campaign that presents doctors with false and misleading claims about Tempus's and Guardant's competing products.

A. While Guardant Experienced Early Success, It Quickly Faltered Once Competitors Like Tempus Entered the Market

24. Within a few years of its founding in 2011, Guardant experienced rapid commercial growth, riding a wave of medical and investor enthusiasm for potential new cancer treatment options, particularly liquid biopsy tests, which *The New York Times* described in 2016 as "one of the hottest trends in oncology."

25. Guardant's early success attracted critical investors from the United States and around the world. In 2017, for example, Guardant raised $360 million in a "gargantuan round of

funding" led by Softbank, a prominent venture capital firm based in Japan. Guardant and Softbank also announced a joint-venture partnership—known as Guardant AMEA—designed "to expand commercialization of Guardant Health's industry-leading liquid biopsy technology in Asia, the Middle East, and Africa."

26. Soon after the Softbank investment, Guardant filed for an initial public offering, which it completed in October 2018.

27. But Guardant's fortunes sank almost as quickly as they had risen, with competitors entering the market with more compelling offerings.

28. One such competitor was Tempus. Soon after its founding, Tempus began growing rapidly by delivering innovative and effective products. In 2024, despite Guardant's seven-year head start, Tempus's total revenue of $693 million approached Guardant's figure of $737 million.

29. Beyond merely establishing itself as a sizable competitor, Tempus also developed a competitive advantage over Guardant by investing in a diversified platform that extended beyond the liquid biopsy testing market. Unlike Guardant, Tempus maintains an array of diagnostic screening assays, including liquid biopsy (where it competes most intensely with Guardant), but also solid-tumor tests, hereditary cancer detection, minimal residual disease testing, and a suite of algorithmic tests designed to assist treating physicians across the entire timeline of cancer detection, treatment, and response monitoring.

30. Tempus also maintains diversified product lines outside the diagnostic testing space, including licensing data to advance precision medicine research, clinical trial matching, and AI-driven applications, all of which are designed to help physicians, academic medical centers, universities, pharmaceutical companies, and biotechnology companies (among others) improve

decision making across health research, drug development, product development, and patient treatment.

31. Guardant lacks similar offerings, although it has tried unsuccessfully over the years to copy Tempus's business model.

32. In 2020, for example, Guardant launched "GuardantConnect," a clinical trial matching service meant to compete with Tempus's TIME program, which had launched a year earlier.

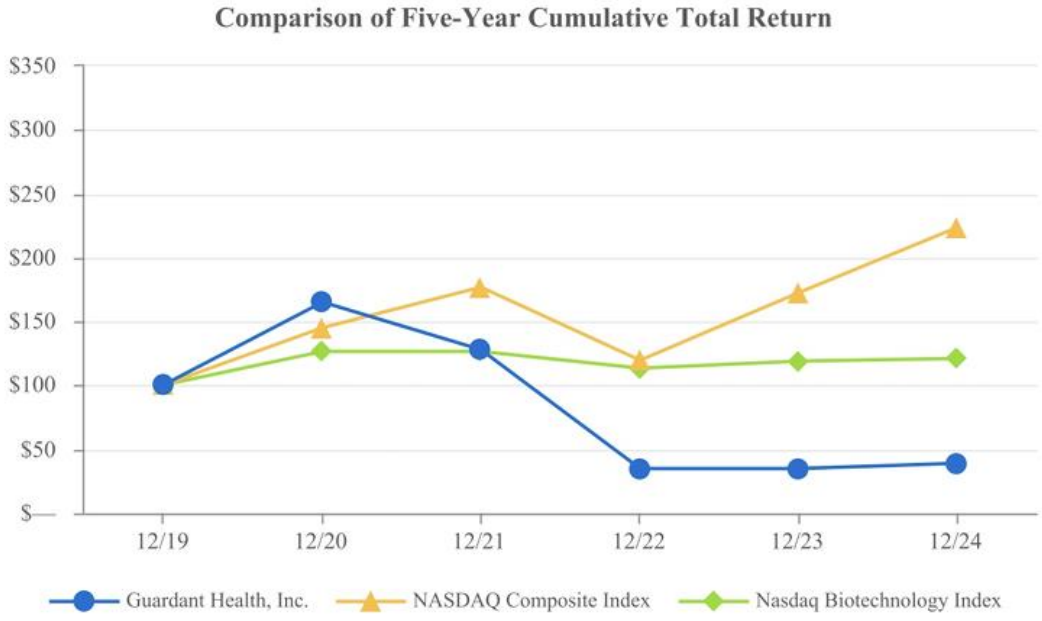
33. Guardant similarly and belatedly attempted to emulate Tempus's focus on data. From its founding, Tempus focused on building a platform that integrated molecular, clinical, and imaging data to enable pharmaceutical and biotechnology companies to improve decision making across the drug lifecycle. Guardant attempted to follow suit in June 2020, when it unveiled its "GuardantINFORM platform," which it marketed as a tool to accelerate drug development by providing biopharma partners with access to a so-called "clinical-genomic" dataset collected through Guardant's liquid biopsy testing.

34. Despite its efforts to replicate Tempus's business model, Guardant has failed to keep pace. Its losses have ballooned in recent years, and Guardant recently warned that it does not expect its cash flows to break even until at least 2028.

35. As Guardant's non-core businesses continued to lag Tempus's, investors and the broader market took notice. For its part, Softbank, which had invested $320 million in Guardant and partnered with them on a joint venture in AMEA, sold its equity stake in Guardant and exited their joint venture. Softbank's departure caused Guardant to spend more than $175 million to buy out its erstwhile partner.

36. Softbank then ramped up its interest and investment in Tempus. In April 2024, Softbank invested $200 million in Tempus's Series G-5 preferred stock offering. In June 2024, Tempus and Softbank announced their own joint venture agreement (with Softbank investing an additional $100 million) to bring Tempus's genomic testing, medical data aggregation and analysis, and AI insights for personalized treatments and therapies to Japan.

37. Other investors apparently saw the same trends as Softbank. After trading at $170 per share in February 2021, Guardant's stock has steadily declined. According to data from Guardant's 2024 10-K, since 2021 its stock has significantly underperformed both the Nasdaq composite index and the more comparable Nasdaq biotech index:



38. Guardant is also burning cash at an alarming rate. In 2023 alone, Guardant burned through $347 million. Since its 2018 IPO, Guardant has repeatedly returned to the public markets to raise more cash by selling additional shares, diluting existing shareholders in the process.

39. By 2024, Guardant faced a critical moment to reverse its fortunes. Struggling to compete on the merits with Tempus in the marketplace and having tried unsuccessfully for years

to mimic Tempus's business practices, Guardant intentionally turned to unlawful tactics to harm Tempus.

B. Guardant's Actions Show Intent to Harm Tempus

40. Guardant's declining market share and its struggles to compete with Tempus's superior technology demanded a fair response, but Guardant did not have one. Instead, Guardant took the low road, setting out to attack Tempus and its business in underhanded, deceitful—and ultimately unlawful—ways. Even before launching its false advertising campaign in late 2024, Guardant took steps to harm Tempus using unfair business tactics that belie the high-minded principles its CEO recently preached in open court. Viewed in combination, Guardant's actions lay bare its intent to harm Tempus.

41. On May 21, 2024, Tempus publicly announced its intention to file for an initial public offering, which occurred on June 14, 2024. On June 11, 2024—three days before Tempus's IPO—Guardant filed a lawsuit alleging that Tempus's liquid biopsy tests infringed several Guardant patents. While Tempus had been selling one of the accused products since 2018, and while some of the asserted patents dated back to 2018, Guardant waited nearly six years (until three days before Tempus's IPO) to file its lawsuit. Guardant then waited 60 days to serve the Complaint on Tempus, further underscoring its true motivation to thwart Tempus's IPO. This effort failed to sour investors, and Tempus completed its IPO as planned.

42. Guardant's strategically timed patent lawsuit was not its only effort to influence investors on Tempus's prospects. Throughout the summer and fall of 2024, Tempus repeatedly fielded questions from investors as to whether Tempus had been improperly billing for its assays (it had not). One industry analyst sent an email to Tempus addressing the billing practice rumor and noted that it "***sounds like it came up from GH [Guardant] on a bus tour***." The "bus tour" referred to a series of meetings during which industry analysts and investors met with Guardant

representatives—an opportunity Guardant seized to spread misinformation about Tempus and its billing practices. These rumors persisted for weeks, necessitating extensive efforts by Tempus to correct the misimpression sowed by Guardant.

43. With its strategically-timed lawsuit and misinformation campaign failing to yield the desired results, Guardant adopted a new tactic. In late summer 2024, Guardant began to target and recruit Tempus's sales reps, who reported repeated outreach from Guardant via LinkedIn messages, emails to personal addresses, and calls to personal cell phones. Guardant's efforts persisted even after the Tempus employees said they were not interested in moving to Guardant.

44. Guardant orchestrated this campaign despite knowing that Tempus's sales reps would be contractually prohibited from calling on the same customers if employed by Guardant. As is standard practice at Tempus, salespeople sign a Confidentiality, Intellectual Property, and Protective Covenants Agreement ("CIPPA") prior to joining the company. These CIPPAs contain standard, commercially reasonable terms prohibiting employees from soliciting Tempus customers for a limited period following their separation from Tempus.

45. Guardant recruited Tempus employees with the intent that they would breach the non-solicit and other similar provisions in their CIPPAs. While Guardant's aggressive recruiting campaign was nationwide, it focused on regions where competition between Tempus and Guardant was highest.

46. In one instance, Guardant tried to recruit a Tempus sales rep to work in the same territory she currently covers for Tempus—in direct violation of her CIPPA.

47. In another instance, Guardant pressed ahead with trying to recruit a Tempus sales rep *even after receiving and reviewing* a copy of his CIPPA. In the summer of 2024, a Guardant recruiter communicated over the phone and in emails with the sales rep, who was at the time

responsible for Tempus accounts in Tucson, Arizona. After an initial conversation, the sales rep wrote it was "great conversing about Guardant's needs for Tucson," confirming that Guardant solicited him to work in the same area he covered for Tempus—and the same area covered by the non-solicit provision of his CIPPA.

48. Immediately after their initial conversation, the Tempus sales rep sent the Guardant recruiter a copy of his CIPPA "for [Guardant's] information and review." Among other things, his CIPPA required that if he left Tempus, he would not for a period of twelve months "directly or indirectly solicit or encourage, attempt to solicit or encourage, or divert business away from any Tempus customer, prospective customer, or any entity or person with whom Tempus has a business relationship" with whom he had been in business contact, or had acquired confidential and proprietary information about, during the prior year.

49. Shortly after reviewing the Tempus sales rep's CIPPA, Guardant offered him a job. Despite knowing of his non-solicitation obligations, Guardant placed him in the sales territory covered by the non-solicit limitations in his CIPPA. Immediately upon joining Guardant, he went to work setting up meetings with his former Tempus customers.

50. Tempus sued the former sales rep on September 19, 2024, as soon as it learned he had breached his CIPPA. Realizing Tempus was serious about enforcing its rights, the sales rep immediately asked his Guardant colleagues to take over the meetings he set up with Tempus customers in violation of his CIPPA—and Guardant's sales reps gladly agreed to do so. Tempus resolved the lawsuit against the sales rep in January 2025, but he remains employed at Guardant. Since his departure, Tempus has seen declining sales in the region he previously serviced for Tempus.

51. This was not the only sales rep whom Guardant successfully induced to violate a contract with Tempus. In October 2024, another sales rep left Tempus for Guardant. On information and belief, that sales rep is covering the same territory with Guardant that she was responsible for at Tempus—again, in violation of her CIPPA.

52. Tempus has suffered harm as a result of Guardant's actions, both by incurring significant costs in enforcing its contractual rights, and from declining sales in the impacted markets.

II. Guardant Engages in a False and Misleading Marketing Campaign to Confuse Doctors About Tempus's Liquid Biopsy Assay

53. Guardant's latest scheme against Tempus targets doctors with a false and misleading head-to-head advertising campaign. Guardant's false ads are designed to confuse physicians by making improper comparisons between the two companies' respective liquid biopsy products—the very tactics that Guardant's CEO denounced in his sworn testimony in November 2024.

A. Tempus's xF+ Test Helps Oncologists Choose Treatments for Their Cancer Patients

54. Both Tempus and Guardant offer laboratory developed tests ("LDTs") in the liquid biopsy space. One of Guardant's tests is called Guardant360. One of Tempus's tests is called xF+.

55. Tempus's xF+ is a blood test administered to cancer patients to detect genetic alterations in their DNA. By identifying which gene alterations are present or absent in a particular patient's DNA, xF+ helps doctors decide which therapies may be most effective against the patient's specific cancer type.

56. Tempus's primary customers for xF+ tests are oncologists, and more than 6,500 oncologists have ordered Tempus's clinical tests. Tempus also offers xF+ tests to cancer researchers, healthcare institutions, and life sciences companies.

57. Tempus's xF+ test competes with Guardant's liquid biopsy tests, including its own laboratory developed test called Guardant360, for many of the same customers.

B. Validating Laboratory Developed Tests Like xF+ and Guardant360

58. Before launching a laboratory developed test like xF+ or Guardant360, companies like Tempus and Guardant perform a series of experiments to demonstrate that the test consistently produces accurate and reliable results. This process is called analytical validation.

59. The Clinical Laboratory Improvement Amendments ("CLIA") set certain standards governing laboratory tests like xF+ and Guardant360. CLIA also leaves certain decisions within the discretion of an individual laboratory.

60. CLIA requires that, before offering a laboratory developed test to treating physicians, the laboratory must verify "certain performance characteristics relating to analytical validity for the use of that test system ***in the laboratory's own environment.***" CLIA cautions, however, that "analytical validation is limited to the specific conditions, staff, equipment, and patient population of the particular laboratory, so ***the findings of these laboratory-specific analytical validation[s] are not meaningful outside of the laboratory that did the analysis.***"

61. Certain performance characteristics relate to a test's ability to detect particular types of gene alterations. Relevant here, both xF+ and Guardant360 are used to identify alterations known as "SNVs," "Indels," and "Fusions."

a. An "SNV" refers to "single nucleotide variant." An SNV is a change to a single nucleotide in a DNA sequence.

b. "Indel" refers to "insertions and deletions." An Indel occurs when a nucleotide is inserted into or deleted from a DNA sequence.

c. A "Fusion" occurs when parts of two different genes are joined together.

62. Identifying SNVs, Indels, and Fusions can be important in understanding disease progression and guiding treatment decisions, particularly for oncology patients.

63. Analytical validation methodologies for detecting alterations like SNVs, Indels, and Fusions vary widely across laboratories. For example, many genetic alterations are difficult to detect, while others are easier. If a laboratory conducts its validation experiments using "easier to detect" genetic variants, that analytical validation process may produce different results—and may lead the lab to report seemingly superior results on the relevant performance characteristics—compared to a laboratory that conducts its validation experiments using "harder to detect" genetic variants.

64. Another example of potential variations in validation processes concerns the reference standards used to conduct experiments. Reference standards are essentially control samples used to set the baseline levels against which the test will be measured. Reference standards may be purchased from third-party manufacturers or generated in-house by a laboratory, and may vary in other ways from one lab to another. The results of the validation may therefore vary depending on the reference standards being used.

65. Tempus and Guardant validate the performance of xF+ and Guardant360 in identifying genetic variants such as SNVs, Indels, and Fusions. Some of the measures relevant here include "variant allele frequency" ("VAF"), "limit of detection" ("LOD"), sensitivity, and specificity.

a. VAF, which is sometimes referred to as mutant allele frequency ("MAF"), is a measurement, expressed as a percentage, that indicates the concentration level of a particular genetic variation within a sample.

b. Limit of detection refers to the lowest amount of a substance (or VAF) within a sample that can be detected with a stated probability. Laboratories can use a number of distinct methodologies to calculate limit of detection.

c. Sensitivity describes the rate at which a test detects a concentration of a substance known to exist within a sample. A test with higher sensitivity reports fewer false negatives.

d. Specificity describes how often the assay correctly detects that a particular mutation is not present in a contrived sample known to be absent of such a mutation. A test with higher specificity reports fewer false positives.

66. The measures above are related in important ways. For example, limit of detection and sensitivity are often assessed or reported together. Limit of detection standing alone may say very little about a particular test's performance. Most tests can detect concentrations of a substance below a particular limit of detection, but the accuracy of such findings may vary widely: a test may detect such lower concentrations only 1 out of 100 times, or the test may detect those lower concentrations virtually all the time.

67. As a result, limit of detection is sometimes calculated at a particular sensitivity level. If a test reports a "limit of detection at a 95 percent sensitivity," that means the test will detect the substance of interest in known samples 95 out of 100 times at the specified limit of detection.

68. Laboratories may adjust their tests to be highly sensitive at low limits of detection (to catch as many positive samples at a particular concentration as possible), but this can come at the expense of a test's specificity. In other words, a laboratory trying to be highly sensitive at a low limit of detection may produce more false positives.

69. Both Tempus and Guardant publicly report certain performance specifications for their respective tests. These publicly available documents, which form the basis for many of the false and misleading claims in Guardant's advertisements, are attached as Exhibit A (xF+ Validation Paper) and Exhibit B (Guardant360 Assay Specifications).

70. As the specification sheets show, xF+ is "designed to capture clinically relevant biomarkers" in approximately 523 genes. Guardant360 "evaluates 740 genes." There is incomplete overlap between the genes covered by the two assays; both tests include substantial numbers of genes not covered by the other panel.

71. Relevant here, Tempus discloses limits of detection applicable to classes of variant genes, including SNVs and Indels. Tempus also discloses a subset of 114 genes "sequenced with enhanced coverage," which have lower limits of detection. For each variant class, Tempus also discloses xF+'s overall sensitivities and specificities, as seen in Exhibit A and in the screenshot below:

xF+ PERFORMANCE SPECIFICATIONS

Variant Class	VAF	Sensitivity	Specificity	LOD
SNVs (Enhanced)	≥0.25%	>99.9%	>99.9%	0.25%
SNVs (Non-Enhanced)	≥1%	>99.9%	>99.9%	1%
INDELs (Enhanced)	≥0.5%	98.0%	>99.9%	0.5%
INDELs (Non-Enhanced)	≥2%	87.5%	>99.9%	2%
CNGs	≥1%	>99.9%	92.0%	1%
Rearrangements	≥1%	96.8%	>99.9%	1%
MSI-H Status	—	90.0%	>99.9%	—
bTMB	—	78.5%	>99.9%	—

72. Crucially, Tempus also clearly discloses its gene list and which genes are in the "enhanced coverage" class. *See* Ex. A at p. 2. Guardant's website claims that "Guardant360 is guideline-complete across all advanced solid tumors" and lists "[c]overed guideline-recommended

biomarkers for common cancer types," but it does ***not*** disclose whether its stated LODs were calculated based on some, all, or none of these. Unlike Tempus, which discloses the sensitivity for each variant class, Guardant reports no comparable specifications for its sensitivities.

73. Assays may detect the presence of biomarkers, even though the presence of the detected biomarker is not reported on the patient's actual clinical report. For example, a test may detect a particular biomarker at a level that cannot be reliably distinguished from background levels of statistical "noise" expected in a normal sample. As with conducting analytical validations and calculating performance specifications, laboratories retain discretion in deciding when the presence of a particular biomarker has medically actionable or reportable implications.

74. For example, when running xF+, Tempus routinely detects SNVs, Indels, and Fusions ***below*** the VAFs stated on the Performance Specification sheet. But Tempus may decide to report those findings as clinically significant on a particular patient's clinical report.

75. Put another way, while the validation process establishes that laboratory tests routinely, reliably, and accurately reproduce certain results, the clinical application of those findings depends on a multitude of factors. And because treating oncologists use the results of these tests to make life-altering decisions for their patients, over-generalizing, making improper comparisons, and asserting false superiority claims can have devastating consequences for patients.

C. Before Targeting Tempus, Guardant Was Unequivocal That Comparative Ads of Diagnostic Tests Were Necessarily False and Misleading

76. Because of the many potential differences in test methodologies used by laboratories to validate LDTs, cross-test comparisons based on reported analytical validation results are fraught with, and often result in, misleading apples-to-oranges comparisons, and cannot legitimately be used to claim that one test is superior to the other.

77. To be meaningful, any comparison between LDTs from different laboratories must be supported by properly designed, head-to-head studies that directly compare the two assays using the same test procedures and protocols.

78. Guardant has never performed a head-to-head study comparing Guardant360 and Tempus xF+.

79. Until its false advertising campaign against Tempus, Guardant took a very public, unequivocal stance regarding the dangers of head-to-head comparisons of diagnostic assays like Guardant360 and xF+. Guardant maintained this stance for years.

80. In a 2017 false advertising lawsuit against another competitor, Foundation Medicine, Guardant declared that data "derived from studies conducted by different researchers, using different patient populations, and having different qualities and characteristics … do not permit a fair or valid comparison."

81. In a 2021 false advertising case against competitor Natera, Guardant again stated unequivocally that "[a]ny valid comparison between diagnostic tests . . . must be supported by properly designed, head-to-head studies that directly compare the two assays using the same test procedures and protocols in the same patient population." Guardant went on: "Cross-test comparisons, especially where the purpose and methodology of the underlying studies differ significantly, and/or where the studies are conducted in different patient populations, ***necessarily lead to a misleading apples-to-oranges result that cannot legitimately be used to claim that one test is superior to the other***."

82. Guardant went on to declare that, when "no reliable [head-to-head] study exists" between two products, any statements comparing those two products "are literally false" under the Lanham Act.

83. Guardant supported its stance against head-to-head advertising with testimony from some of its most senior leaders. In a June 13, 2021 sworn declaration submitted in support of its case against Natera, Guardant Vice President for Clinical Development, Justin Odegaard, reiterated that "[t]o be meaningful, any comparison between diagnostic tests … must be supported by properly designed, head-to-head studies that directly compare the two assays using the same test procedures and protocols in the same patient population. Cross-test comparisons, especially where the purpose and methodology of the underlying studies differ significantly, and/or where the studies are conducted in different patient populations, are fraught with, and often result in, misleading apples-to-oranges comparisons that cannot legitimately be used to claim that one test is superior to the other."

84. In a separate declaration filed in the same lawsuit, Guardant's Senior Medical Science Liaison, Thereasa Rich, called it a "fundamental principle" that "any valid comparison between diagnostic tests . . . must be supported by properly designed studies that directly compare the two assays using the same test procedures and protocols and in a comparable patient population."

85. Guardant maintained this position throughout its extensive litigation with Natera. Indeed, in November 2024, just weeks before launching its false advertising campaign against Tempus, Guardant's co-CEO and co-founder, Helmy Eltoukhy, took the witness stand to affirm the dangers of head-to-head comparisons between diagnostic assays. His testimony about Guardant's advertising policies was clear: "We take sort of the high road. We always just focus on our own products … our products should really stand on their own." He went on to say that "we really instruct our marketing team, sales team and so on, to make sure we're just talking about the merits of our own products." When asked if "Guardant engage[s] in comparative advertising

against its competitors," his answer was unequivocal: "No, we don't." Eltoukhy was also clear about the real-life dangers of false and misleading advertising claims, referring to patients whose lives were saved by testing: "[I]f, you know, people suspected that test wasn't, you know, useful or, you know, didn't perform well, they wouldn't use it and patients like that wouldn't be here today."

86. A product director at Guardant, Kristin Price, reaffirmed its co-CEO's testimony on the stand: "it's certainly not in my ethos and not in the ethos of our company to trash a competitor." When asked "Did you believe that trashing your competitor may undermine oncologists', cancer doctors' faith in the science altogether?" Price responded: "Yeah. It could add years of time that it would take to build up kind of comfort and knowledge with the new technology."

87. But while Guardant's co-CEO and product director were testifying in open court about the perils of head-to-head comparisons involving liquid biopsy assays, and claiming that Guardant took the "sort of high road" in their advertisements, focusing solely on their own products, Guardant was launching its very own misleading head-to-head comparison advertising campaign against Tempus.

D. Guardant's Ads Comparing xF+ and Guardant360 Are False and Misleading

88. As discussed in more detail below, Guardant's ads comparing its Guardant360 with xF+ are false and misleading for multiple reasons.

89. First, Guardant makes head-to-head comparisons of the two assays' performance specifications without a proper head-to-head study. As Guardant has itself said in prior litigation, such comparisons are "literally false."

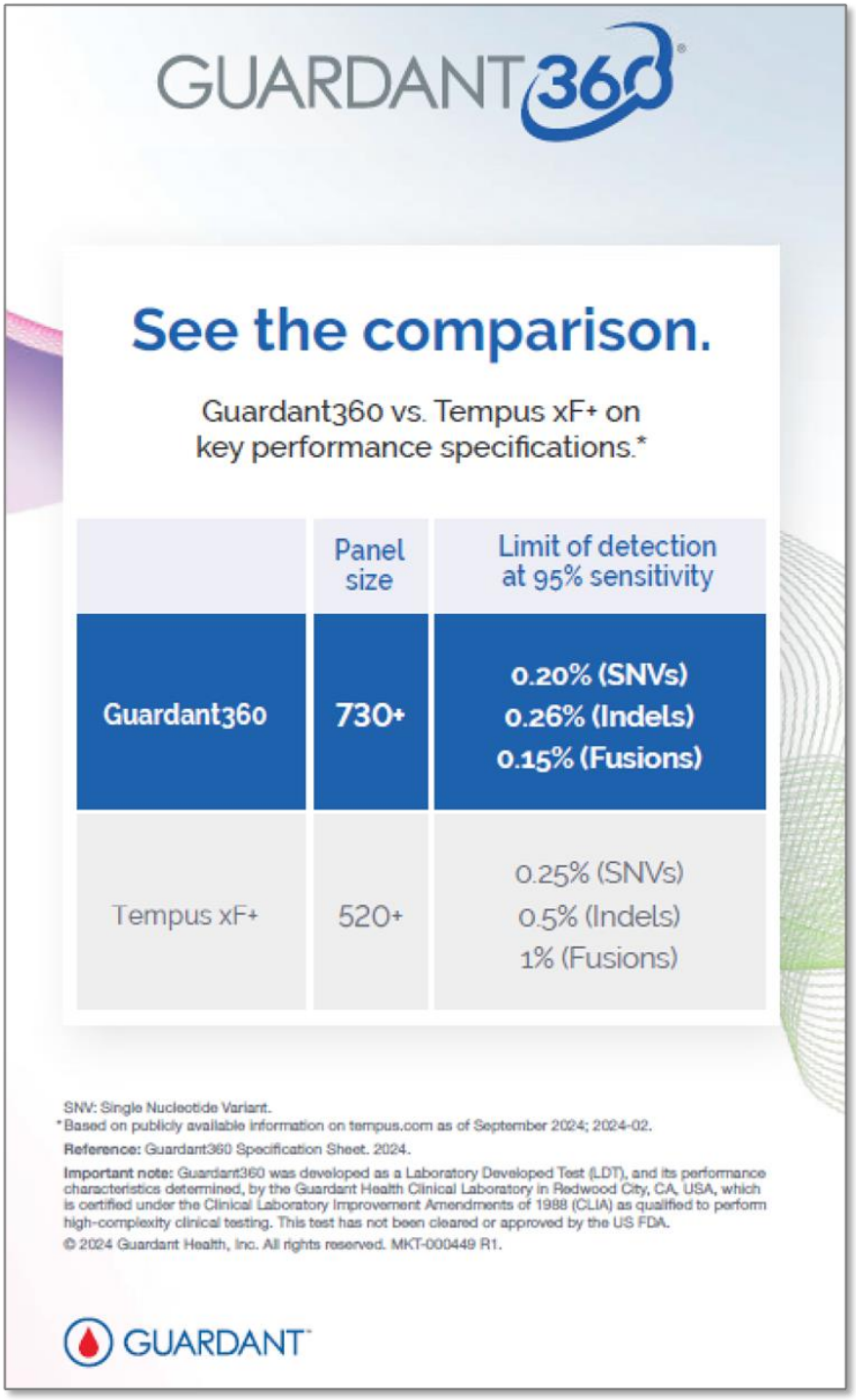
90. Second, Guardant misrepresents Tempus's and Guardant's performance characteristics in fundamental ways, through express misrepresentations and deliberate omissions.

These include misrepresentations about the relative sensitivity of the tests, among other characteristics.

91. Third, Guardant makes misleading and false statements, both express and implied, about the impact of the tests' relative performance characteristics on patient outcomes, which is exactly why Guardant's ads target physicians. Guardant's misrepresentations could have a real-life, negative impact on the cancer patients these physicians treat.

1. Guardant's "See the Comparison" Ad Is False and Misleading

92. In 2024, Guardant began disseminating an ad to healthcare professionals (including Tempus's existing customers) that purports to compare "Guardant360 vs. Tempus xF+ on key performance specifications" (referred to as "See the Comparison" advertisement). The ad is reprinted on the following page and attached as Exhibit C.



93. Guardant's "See the Comparison" ad is false and misleading for multiple reasons.

94. The side-by-side comparison is, by itself, misleading. By placing the specifications side-by-side under the heading "See the Comparison":

a. Guardant falsely suggests that Guardant360 and xF+ have been tested head-to-head;

b. Guardant falsely claims that the numbers presented are comparable despite the fact that each laboratory used distinct methodologies and made distinct decisions regarding which inputs to use to calculate performance metrics. For example, Guardant does not disclose either the method it used to calculate the limit of detection, which variants or how many were included in its validation testing, or the methodological details of its analytical validation. Absent this basic information, and to quote Guardant in its prior litigation, any head-to-head comparisons "necessarily lead to a misleading apples-to-oranges result that cannot legitimately be used to claim that one test is superior to the other."

c. Guardant induces the recipients (*i.e.*, the physicians to whom Guardant disseminated the ad) to draw conclusions about each test's performance when any such conclusions are improper absent additional information.

95. Guardant does not disclose its own analytical validation processes.

96. Guardant does not have access to Tempus's analytical validation processes.

97. Guardant also cherry picks information in the "See the Comparison" ad in a way that leaves false impressions. For example, the ad lists xF+'s reported LODs without noting that that the Tempus xF+ Validation Paper also states expressly that "[s]elect variants may be reported at VAFs lower than 0.25%," below the reported LOD. *See* Ex. A. As discussed below, the omission of this fact (and other information in the Tempus Validation Paper) is misleading.

98. The xF+ Validation Paper states that Tempus sequences "114 genes" with "enhanced coverage and lower limit of detection (0.25% VAF for SNVs)." Ex. A. Tempus lists the 114 genes that comprise this enhanced coverage region, allowing a reader to understand the

specific genes that Tempus tests to a lower limit of detection. The 114 genes include those genes that have been proven "actionable" in some way in the treatment of cancer patients.

99. But while Guardant's ad omits critical information about Tempus, it also leaves out information about Guardant360. In the fine print contained in the cited Guardant360 Assay Specifications, Guardant notes that its listed limit of detection values—the very metric that Guardant claims is superior to xF+—were measured using "oncogenic variants and genes with relevance in guidelines, drug labels, and clinical trials." *See* Ex. B. Guardant does ***not*** disclose which genes it believes have relevance in clinical guidelines, drug labels, or clinical trials. Without disclosing more, comparing a limit of detection based on an unknown and unknowable number of genes is misleading.

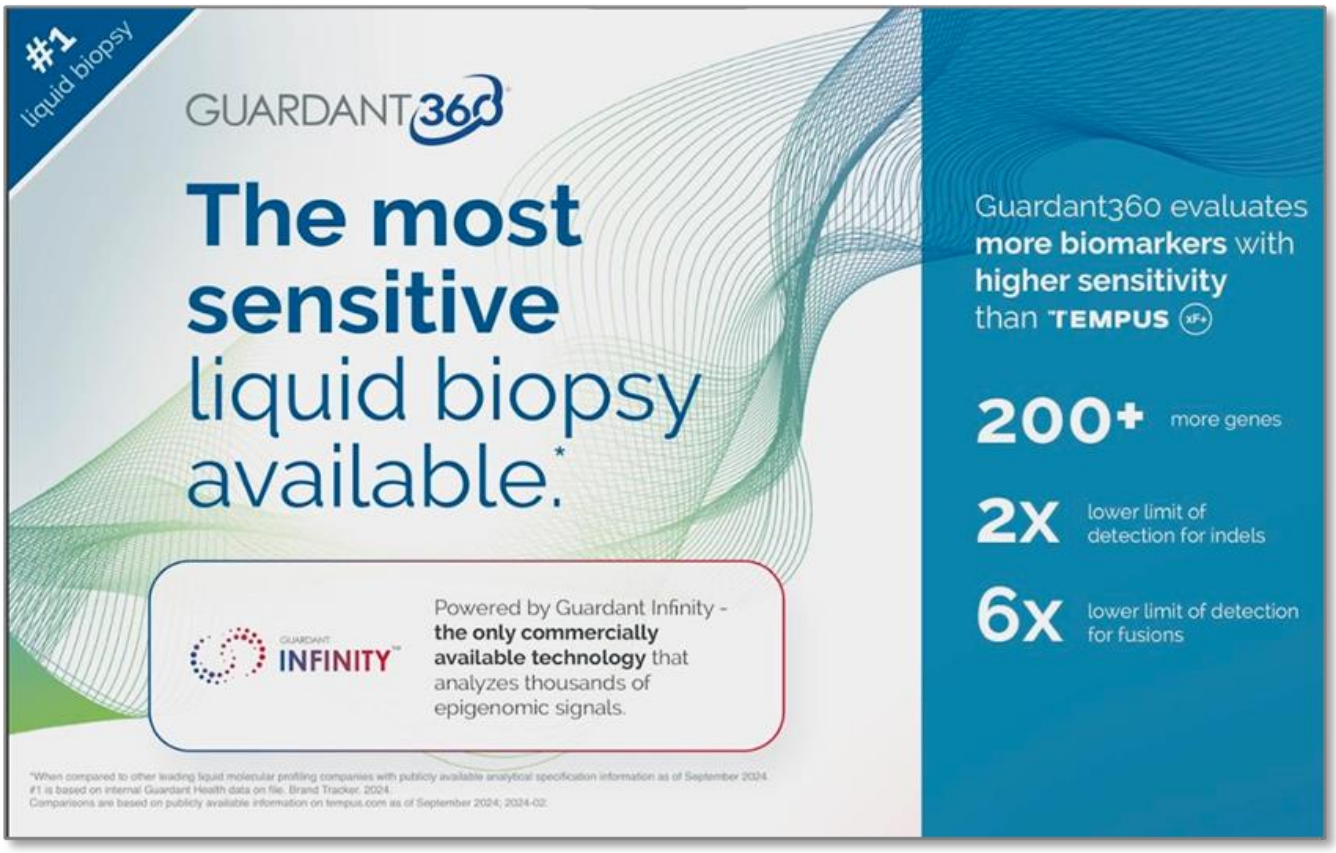
100. Put another way, Guardant's claimed superior limits of detection are based on a subset of their 740 genes, but Guardant does not disclose how many of those 740 genes, which genes, or any other information that would allow even an intelligible, let alone legitimate, comparison of limits of detection. By placing the performance metrics next to the panel size counts for both tests, the advertisement falsely and misleadingly suggests that the reported metrics apply to all of Guardant360's "730+" genes and all of xF+'s "520+" genes. Neither is true.

101. Finally, by referring to "key performance specifications" in its advertising, Guardant falsely and misleadingly implies to physicians and patients that the purported comparisons are based on clinical performance data derived from studies on patients from the intended use populations in a clinical setting. Rather than take steps to dispel any potential false impression the audience may form about the nature of the data, Guardant intentionally omits any reference to the fact that it is analytical data—not clinical data—being compared.

102. In its 2017 lawsuit against Foundation, Guardant faulted Foundation for the very same conduct in which it engages here—falsely implying that data in its ad "refer[red] to **clinical** (not analytical) performance" (emphasis in original). Yet again, Guardant's statements in its own prior lawsuit reveal the willfulness with which it engaged in the same false and misleading advertising against Tempus.

2. Guardant's Ad Claiming to Be the Most Sensitive Liquid Biopsy Test Available Is False and Misleading

103. Guardant's "Most Sensitive" ad, pictured below and attached as Exhibit D, suffers from the same false and misleading claims as the "See the Comparison" ad and makes yet further false and misleading direct comparisons between Guardant360 and xF+.



104. The claims made in the Most Sensitive ad, considered individually and together, are false and misleading for additional reasons than those described above.

105. The "Most Sensitive" ad is literally false both through multiple misrepresentations and omissions, as described below:

a. The ad expressly and falsely claims that "Guardant360 evaluates **more biomarkers** with **higher sensitivity** than **Tempus,**" which, according to Guardant makes Guardant 360 "**the most sensitive**" liquid biopsy assay available (emphasis in original). But the only data Guardant has to compare xF+ and Guardant360 does not support Guardant's claim. To take only one example, if one could make head-to-head comparisons between assays and accepting Guardant's characterizations, for SNVs, Guardant360 would have a limit of detection of 0.20% while xF+ would have a limit of detection of 0.25%. But having a lower limit of detection does not necessarily make one test more sensitive than the other. As discussed above, limit of detection can be calculated at different sensitivity levels, and limit of detection standing alone may say very little about a particular test's performance. Put simply, the ad's primary comparative assertion—that Guardant360 is "the most sensitive liquid biopsy available" or has a "higher sensitivity" than xF+—muddles the difference between sensitivity and limit of detection in a way that is false and misleading.

b. Guardant's assertion also implies that the limit of detection is lower for every one of the biomarkers that Guardant purports to test (or the "sensitivity is higher" as Guardant conflates the terminology). This statement also implies that Guardant360 is more sensitive or has a lower limit of detection than Tempus' xF+ for every biomarker. These claims are literally false; Guardant has not conducted validation testing that establishes Guardant360's sensitivity for ***every*** biomarker. Guardant does not even report the biomarkers included in its validation testing or upon which its reported limit of detection is based, so Guardant has no basis

to say or suggest that it evaluates ***every*** biomarker in its test panel at a higher sensitivity than ***every*** biomarker in Tempus's test panel.

c. Likewise, the claim that Guardant360 "evaluates more biomarkers" than xF+ is irrelevant to sensitivity. The "200+ more genes" covered by Guardant360 may not be clinically actionable, and they may not even have the higher sensitivity that Guardant claims. As discussed above, Guardant does not publicly report sensitivity numbers for the 200+ genes mentioned in the ad.

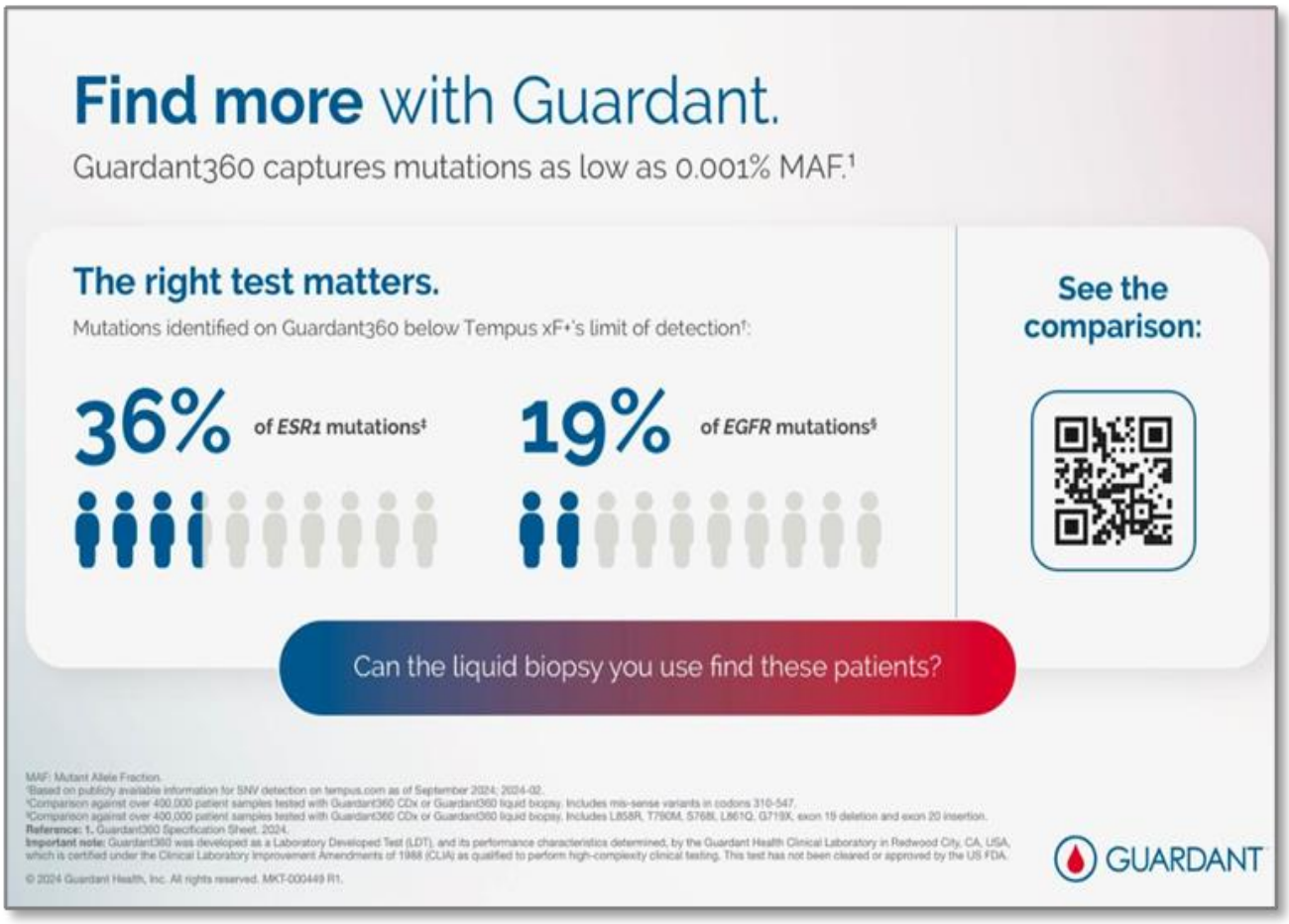
d. The "Most Sensitive" ad also makes a critical omission. The ad purports to base its "most sensitive" assertion "compared to other leading liquid molecular profiling companies with publicly available analytical specification information as of September 2024." Unlike Tempus, however, Guardant does not publicly disclose overall sensitivities for Guardant360. While the publicly available xF+ Validation Paper reports >99.9% sensitivity for SNVs, 98.0% sensitivity for INDELs, and 96.8% sensitivity for Fusions (rearrangements), the publicly available Guardant360 Assay Specification omits any comparable information on sensitivity.

106. Third, the "Most Sensitive" ad is misleading from a clinical perspective. By framing the purported limit of detection comparisons as multiples, omitting the underlying raw numbers, and making unsupported superiority claims about sensitivity, Guardant's "Most Sensitive" ad deliberately misleads and confuses doctors about the purported clinical significance of the comparison. Guardant distributed the ad hoping doctors would conclude that Guardant360 is more sensitive than xF+ (false) and therefore is more beneficial to patients suffering from cancer (also false).

107. Guardant's sales representatives have distributed the "Most Sensitive" ads to doctors around the country with precisely this intent—inviting doctors to conclude that Guardant's sensitivity is clinically superior when the facts do not support such a claim.

3. Guardant's "Find More" Ad Is False and Misleading

108. Guardant is also disseminating an ad to healthcare professionals (including Tempus's existing customers) that alleges physicians can "find more" genetic mutations with the Guardant360 test than the xF+ test (referred to as the "Find More" advertisement). The ad is reprinted below and attached as Exhibit E.



109. Guardant's "Find More" ad claims that Guardant360 identifies 36% of ESR1 mutations below xF+'s limit of detection. An ESR1 mutation is a change in the ESR1 gene, found most often in breast or endometrial cancer patients, which causes cancer to grow.

110. Guardant's ad also claims that Guardant360 identifies 19% of EGFR mutations below xF+'s limit of detection. An EGFR mutation is a change in the EGFR gene, found most often in non-small cell lung cancer, which causes cancer to grow.

111. The "Find More" ad falsely claims the Guardant360 test is superior to the xF+, because it can find these "extra mutations" and suggests that xF+ cannot. Guardant's claims in the "Find More" ad are false and misleading for several reasons.

112. First, the "Find More" ad suffers from the same head-to-head infirmities discussed throughout this Complaint and others. For example:

a. The advertisement is not based on data from a single Tempus test. Guardant performed no analysis of the number of mutations xF+ detects. Guardant did not analyze the actual rate at which the Tempus test reported ESR1 mutations or EGFR mutations. There was no head-to-head study between the two tests that revealed Guardant's test could find extra mutations. Instead, Guardant purportedly identified the extra mutations solely on ***its own data***, from ***its own tests***. In tiny print, Guardant claims its comparison between Guardant360 and xF+ is based on "over 400,000 patient samples tested with Guardant360CDx or Guardant360 liquid biopsy." In other words, Guardant uses its own non-public data to artificially compare what it claims is its test's real-world performance against xF+'s analytical specifications, rather than comparing both tests' real-world results. Guardant's claim that its test can "find more" mutations than the xF+ is false and unsupported by clinical data.

b. Compounding the problem, when Guardant compared xF+'s spec sheet with Guardant360's alleged clinical performance, Guardant relied on the test results from a third, separate and distinct assay, ***Guardant360CDx***. In other words, Guardant appears to analyze test results produced by Guardant360 CDx when making claims about Guardant360 LDT's performance relative to xF+.

113. Second, the "Find More" ad is riddled with other misrepresentations and omissions that make it both false and misleading:

a. The advertisement falsely implies that xF+ does not report below its limit of detection and cannot detect mutations below its limit of detection. But Tempus does, in fact, report mutations below the limit of detection. The information on Tempus's website, on which Guardant purportedly relied in making its false claims, states expressly that certain variants may be reported at lower VAFs per pathologist discretion. Guardant's ad intentionally omits this fact. It pretends that xF+ does not report VAF lower than 0.25% in order to make its false and misleading claim that Guardant360 finds more mutations.

b. Similarly, at least some of the "extra mutations" that Guardant claims to identify fall below Guardant's *own* limit of detection. The ad states: "Guardant360 captures mutations as low as 0.001% MAF." In making the claim that its test can find more patients, Guardant counts any patient with an identified variant, ***even if the patient's variant falls below Guardant's limit of detection***. But Guardant has a bright line cut-off at Tempus's limit of detection, even though Tempus also captures mutations far below its LOD. Guardant's claim in the Find More ad is therefore literally false.

114. Third, the confusion caused by the "Find More" ad in the clinical context is reckless.

a. The "Find More" ad implies that Guardant360 test will "identify" or "capture" mutations below Guardant's own limit of detection, without discussing the specificity of these identifications or captures, and without acknowledging the risk that results below Guardant360's LOD may include false positives. As discussed above, a laboratory test with lower specificity results in more false positive results. The absence of this information in Guardant's ad makes it impossible for a clinician to evaluate Guardant's claims.

b. More egregiously, the Find More ad misleadingly declares that Guardant360 can ***identify*** mutations below its limit of detection, but the ad does not say whether Guardant would ***clinically report*** such identified mutations as a clinical finding on which an oncologist should base a treatment decision.

c. The consequences of false positives can be serious for cancer patients and their treatment decisions, especially for reported ESR1 and EGFR mutations.

d. For example, clinical guidelines recommend that non-small cell lung cancer patients with EGFR mutations in the adjuvant stage of treatment should be placed on an EGFR inhibitor and forego immunotherapy. A patient falsely diagnosed with an EGFR mutation may be therefore deemed ineligible for lifesaving immunotherapy, while being put *on* extra medication that is at best ineffective, and at worst causes side effects like interstitial lung disease.

e. False positives are just as dangerous for ESR1 mutations. Clinical guidelines recommend that breast cancer patients with ESR1 mutations should be placed on an estrogen receptor antagonist (such as Fulvestrant) and forego taking an antibody drug conjugate. A breast cancer patient falsely diagnosed with an ESR1 gene mutation may therefore forego an effective antibody drug treatment while being placed on unnecessary ESR1 medication.

f. Because of the potentially life-threatening consequences of a false positive, Tempus chooses not to report certain variant findings at lower VAFs. In other words, just because Tempus (or for that matter, Guardant) ***can*** identify more gene mutations in an analytical context, doesn't mean it ***should*** do so in a clinical context.

g. Guardant's "Find More" ad is presented without the context of other performance criteria that would be critical to evaluating the risk of false positives, including specificity. That has real-world implications for doctors trying to choose life-saving treatments for their patients, particularly those with EGFR and ESR1 mutations.

115. Guardant willfully disseminated the "Find More" ad (and the other ads described herein) to doctors around the country knowing it was false and misleading. Guardant's willfulness is clear from (1) its prior course of conduct attacking Tempus, and (2) the fact that it previously sued other competitors for disseminating the very same type of ad. In 2017, Guardant sued Foundation Medicine for advertising that Foundation's product "has uncovered what [Guardant360] ha[s] missed"—much like Guardant now claims doctors can "find more" by using Guardant360 instead of Tempus.

116. In that case, Guardant faulted Foundation for warning of a "profound clinical impact" and "impl[ying] that use of Guardant360 could cost a patient her life, while use of the [Foundation Assays] could save it." Guardant decried Foundation for "[s]eeking to capitalize on the concerns of patients and their doctors about the consequences of inaccurate tests, as well as to influence oncologists and others to use the [Foundation Assays] instead of Guardant360."

117. Guardant has now employed the very same tactics against Tempus that formed the basis for its lawsuit against Foundation. Guardant's conduct here is not just hypocritical; it is illegal, willful, reckless, and wanton.

E. Guardant's False Advertising Is Causing Significant Confusion

118. The Guardant sales force is using at least the advertisements discussed above to spread additional misinformation about Tempus. The ads are false and misleading on their face.

119. In addition, Guardant's sales force is relying on the ads to disseminate additional false and misleading messages. For example, a Guardant sales employee emailed an existing Tempus customer and wrote: "I know we have had a hard time connecting in-person so I wanted to just make sure you realize that when compared with Tempus XF+ [sic] Guardant 360 has 2x the lower limit of detection for Indels and 6x lower limit of detection for fusions."

120. The claim of superiority in the Guardant salesperson's email is false.

121. The Guardant sales representative also wrote: "This matters to your patients because using a less sensitive liquid biopsy **could be missing options for your patients**" (emphasis in original). The customer forwarded Guardant's email to Tempus and invited a Tempus sales rep to "share any thoughts on this" in response to Guardant's misleading ad.

122. As discussed above, the statements that the Tempus xF+ is "less sensitive" and that doctors using it "could be missing options" are false and misleading.

123. On information and belief, Guardant has provided similar talking points to its sales personnel for use when talking to existing Tempus customers. On information and belief, Guardant sales personnel have utilized similar false and misleading talking points in their communications with potential customers.

124. Tempus's physician customers across the country have contacted Tempus to inquire about Guardant's misleading advertisements. The physicians have asked questions indicating the advertisement is causing confusion in the marketplace. Guardant's false statements, made both in its printed ads and by its salesforce, are material to the doctors, researchers, and healthcare institutions to whom they are made, because they are directed toward accuracy,

reliability, and sensitivity—critical considerations for any diagnostic tool, and especially one used in the treatment of cancer.

125. Guardant's misleading claims harm not only Tempus, but also the doctors, patients, and researchers who may elect not to use xF+ due to Guardant's misstatements. As exemplified by the exchange above, Guardant preys on healthcare professionals' concern for their patients by suggesting that Tempus's xF+ "could be missing options for your patients." It is difficult to think of a false and/or misleading statement more material than one purporting to affect the treatment options for a cancer patient.

126. As Guardant's Vice President for Clinical Development testified under oath, "[o]ncologists do not have the means, resources or opportunities to independently test and validate new technology. As a result, they must rely on the accuracy of information placed before them by medical liaisons, sales representatives, promotional publications, and information presented at public meetings." Therefore, misleading doctors with false ads "deprive[s] patients of the benefits" of a necessary test or drug.

127. That is exactly what Guardant has done here. By presenting false comparisons between Guardant360 and Tempus xF+ to oncologists and the medical community, Guardant has "deprived patients of the benefits" of Tempus xF+.

128. Guardant's efforts to deprive patients of the benefits of Tempus xF+ has been to its financial benefit. Physicians in multiple states have switched from using Tempus's xF+ test to Guardant's test after visits from Guardant sales representatives. Upon information and belief, those sales representatives shared the misleading advertising materials mentioned above. Likewise, at certain healthcare facilities where Guardant has targeted its marketing efforts, Tempus's sales of

the xF+ have declined while sales of its other products have not. These financial gains for Guardant come at the expense of the treatment of the patients and doctors Guardant has deceived.

129. Accordingly, Tempus brings this action to stop Guardant's campaign of false and misleading advertising practices and unlawful competition.

COUNT I:
FALSE ADVERTISING IN VIOLATION OF THE LANHAM ACT (15 U.S.C. § 1125)

130. Tempus incorporates by reference all allegations set forth above as if fully set forth herein.

131. Guardant's conduct constitutes false and misleading statements about its own goods and services and a competitor's goods and services in violation of Section 43(a) of the Lanham Act.

132. Guardant made false and misleading statements about Tempus's products, including the statements made in Guardant's "See the Comparison," "Most Sensitive," and "Find More" ads.

133. Guardant's false and misleading statements are designed to, did, and will continue to, mislead doctors, patients, cancer researchers, healthcare institutions, life sciences companies, and others into believing that Guardant360 performs better than it actually does, and that it is superior to Tempus's xF+.

134. Guardant's false and misleading statements relate to goods that traveled in interstate commerce.

135. Guardant intended for its false and misleading statements to deceive doctors, patients, cancer researchers, healthcare institutions, life sciences companies, and others about the quality and performance of its test relative to Tempus's xF+.

136. Guardant's false and misleading statements are material to doctors, patients, cancer researchers, healthcare institutions, life sciences companies, and others, and have influenced their decisions to purchase Guardant's products over Tempus's.

137. Tempus has suffered, and will continue to suffer, significant harm as a result of Guardant's false and misleading statements, including lost revenue, loss of goodwill, and diminished reputation.

138. Tempus is entitled to all relief available under 15 U.S.C. § 1117(a), including disgorgement of Guardant's profits, actual damages, treble damages, and attorneys' fees and costs.

139. Unless enjoined by this Court, Guardant's acts will irreparably diminish Tempus's market share and injure its goodwill and reputation, for which Tempus has no adequate remedy at law. Tempus is entitled to preliminary and permanent injunctive relief under Section 1116 of the Lanham Act.

COUNT II: FALSE ADVERTISING IN VIOLATION OF CAL. BUS. & PROF. CODE § 17500 ET SEQ.

140. Tempus incorporates by reference all allegations set forth above as if fully set forth herein.

141. Under California law, it is unlawful "to make or disseminate or cause to be made or disseminated from this state" false or misleading statements to "induce the public to enter into any obligation relating" to property or services. Cal. Bus. & Prof. Code § 17500.

142. It is also unlawful for "any person doing business in California and advertising to consumers in California to make any false or misleading advertising claim, including claims that (1) purport to be based on factual, objective, or clinical evidence, that (2) compare the product's effectiveness or safety to that of other brands or products, or (3) purport to be based on any fact." Cal. Bus. & Prof. Code § 17508.

143. Guardant's false and misleading statements about Tempus's products, including the statements made in Guardant's "See the Comparison," "Most Sensitive," and "Find More" ads, violate Cal. Bus. & Prof. Code §§ 17500 & 17508.

144. Tempus is entitled to all relief available under Cal. Bus. & Prof. Code § 17535, including restitution, injunctive relief, and any other available relief.

145. Unless enjoined by this Court, Guardant's acts will irreparably diminish Tempus's market share and injure its goodwill and reputation, for which Tempus has no adequate remedy at law. Tempus is entitled to preliminary and permanent injunctive relief.

COUNT III: CALIFORNIA UNFAIR COMPETITION LAW

146. Tempus incorporates by reference all allegations set forth above as if fully set forth herein.

147. Under California law, "unfair competition shall mean and include any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code § 17200.

148. Guardant's false and misleading statements about Tempus's products, including the statements made in Guardant's "See the Comparison," "Most Sensitive," and "Find More" ads, violate Cal. Bus. & Prof. Code § 17200.

149. Additionally, Guardant's inducement of Tempus sales representatives to violate their contractual agreements constitutes unfair competition within the meaning of Cal. Bus. & Prof. Code § 17200.

150. Guardant's recruiting of Tempus's sales representatives and efforts to have them violate their non-solicit agreements also constitutes unfair competition.

151. Tempus is entitled to all relief available under Cal. Bus. & Prof. Code § 17203, including restitution, injunctive relief, and any other available relief.

152. Unless enjoined by this Court, Guardant's acts will irreparably diminish Tempus's market share and injure its goodwill and reputation, for which Tempus has no adequate remedy at law. Tempus is entitled to preliminary and permanent injunctive relief.

COUNT IV: DECEPTIVE TRADE PRACTICES

153. Tempus incorporates by reference all allegations set forth above as if fully set forth herein.

154. Under the Delaware Uniform Deceptive Trade Practices Act ("DTPA"), it is unlawful to "[d]isparage[] the goods, services, or business of another by false or misleading representation of fact." 6 Del. C. § 2532(a)(8).

155. The Illinois Uniform Deceptive Trade Practices Act provides the same. 815 ILCS 510/2(a)(8).

156. The DTPA also makes it unlawful to "[r]epresent[] that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have." 6 Del. C. § 2532(a)(5); 815 ILCS 510/2(a)(5).

157. Guardant has intentionally engaged in deceptive trade practices.

158. Guardant has disparaged Tempus's products by making false and misleading representations of fact regarding the performance of Tempus's products, including in Guardant's "See the Comparison," "Most Sensitive," and "Find More" ads. Guardant has also engaged in a deceptive trade practice by representing its own Guardant360 assay has characteristics, benefits, and qualities that it does not have.

159. Guardant has willfully engaged in these deceptive trade practices, entitling Tempus to attorneys' fees and costs.

160. Because Tempus is entitled to damages under its state common law claims, Tempus is entitled to treble damages under 6 Del. C. § 2533(c).

COUNT V: COMMON LAW UNFAIR COMPETITION

161. Tempus incorporates by reference all allegations set forth above as if fully set forth herein.

162. Tempus is one of Guardant's primary competitors.

163. Guardant, by engaging in the acts described above, is and has been unlawfully competing with Tempus.

164. Guardant has disseminated and caused others to disseminate false and misleading statements about Tempus's xF+. Its promotional materials and other statements constitute false and deceptive advertising and are likely to mislead, and have misled, consumers about the nature, characteristics, and quality of Tempus's product. These statements directly target Tempus and were intended to diminish or destroy Tempus's reputation, goodwill, and market position.

165. Guardant is willfully, knowingly, and intentionally making false statements in advertising, and unless enjoined by this Court, will continue to deceive, mislead, and confuse consumers into believing that, among other things, Guardant360 is superior to xF+. Guardant's false and deceptive advertising is intended to cause, and did in fact cause, consumers to choose to do business with Guardant instead of Tempus, and diminished Tempus's goodwill and market position.

166. Guardant's recruiting of Tempus's sales representatives and efforts to have them violate their non-solicit agreements also constitutes unfair competition.

167. As a direct and proximate result of Guardant's conduct, Tempus has suffered, and will continue to suffer, irreparable harm. Tempus has no adequate remedy at law.

168. As a direct and proximate result of Guardant's conduct, Tempus has suffered, and will continue to suffer, monetary damages, including business opportunities lost to Guardant based on Guardant's false and misleading statements to Tempus's potential and current customers.

169. Guardant's tortious conduct is wanton, willful, and reckless, and Tempus is entitled to punitive damages.

COUNT VI: TORTIOUS INTERFERENCE WITH KNOWN CONTRACTUAL RELATIONS

170. Tempus incorporates by reference all allegations set forth above as if fully set forth herein.

171. Tempus's sales representatives, including ones later hired by Guardant, knowingly, and for valid consideration, entered into a written a Confidentiality, Intellectual Property, and Protective Covenants Agreement ("CIPPA") with Tempus.

172. Under the terms of the CIPPA, the sales representative agreed that if he subsequently left Tempus he would not for a period of twelve months "directly or indirectly solicit or encourage, attempt to solicit or encourage, or divert business away from any Tempus customer, prospective customer, or any entity or person with whom Tempus has a business relationship."

173. On information and belief, Guardant knew of the existence of the sales representative's CIPPA with Tempus; indeed, a Guardant recruiter asked him to send her a copy of his CIPPA and acknowledged that Guardant was reviewing it internally.

174. Despite reviewing the CIPPA, Guardant hired Tempus's sales representative and placed him in the exact same territory covering the exact same physician practices that he had developed while working for Tempus.

175. Guardant intentionally and knowingly induced Tempus's sales representative to breach the non-compete and non-solicit provisions of the CIPPA. Guardant's tortious conduct included encouraging him to call on and set up meetings with customers covered by his CIPPA.

176. As a direct and proximate result of Guardant's intentional interference with the CIPPA, Tempus has suffered, and will continue to suffer, monetary damages, including loss of business from Tempus customers that Tempus's sales representative once serviced.

177. Guardant has likewise intentionally and knowingly interfered with Tempus's CIPPAs with other sales reps. Guardant has hired other Tempus sales reps, placed them in the same territories as the ones they covered for Tempus, and encouraged them to solicit Tempus customers in violation of their CIPPAs.

178. Guardant's conduct in interfering with Tempus's CIPPAs exhibits a wanton or willful disregard for Tempus's rights, and Tempus is entitled to punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Tempus respectfully asks this Court to award the following relief:

179. A judgment that Guardant has violated the Lanham Act, including through its promotion and dissemination of the "See the Comparison," "Most Sensitive," and "Find More" ads;

180. A judgment that Guardant has violated California false advertising law, including through its promotion and dissemination of the "See the Comparison," "Most Sensitive," and "Find More" ads;

181. A judgment that Guardant has violated the California Unfair Competition Law, including through its promotion and dissemination of the "See the Comparison," "Most Sensitive," and "Find More" ads;

182. A judgment that Guardant has violated the Uniform Deceptive Trade Practices Act, including through its promotion and dissemination of the "See the Comparison," "Most Sensitive," and "Find More" ads;

183. An injunction enjoining Guardant and its officers, employees, directors, agents, servants, affiliates, divisions, branches, subsidiaries, parents, and all others acting on behalf of or in active concert or participation with, from:

a. publishing or disseminating the "See the Comparison" ad, the "Most Sensitive" ad, and the "Find More" ad;

b. publishing or disseminating any other false statements comparing Guardant's products with Tempus's products, including statements comparing Guardant360 to Tempus's xF+;

c. inducing Tempus employees to breach their contractual obligations to Tempus; and

d. engaging in any other activity constituting unfair competition.

184. An order requiring Guardant to take all necessary corrective measures to correct the false and misleading impressions created among healthcare professionals and others by its false advertising;

185. An award of actual monetary damages, including, but not limited to, Tempus's lost profits, lost business opportunities, harm to Tempus's reputation and goodwill, and Guardant's ill-gotten and unjustly derived revenues;

186. An award of punitive and exemplary damages;

187. An award of pre- and post-judgment interest to the extent permitted by law;

188. Costs in bringing and defending this litigation, including expert witness fees, to the extent permitted by law;

189. Attorneys' fees, to the extent permitted by law;

190. Statutory damages, including multipliers, trebling, and equitable enhancements, to the extent permitted by law; and

191. Any other relief at law or equity as the Court may deem just and proper.

TEMPUS'S ANSWER TO GUARDANT'S COMPLAINT

Tempus demands a trial by jury on all issues so triable. Tempus denies any allegation in the Complaint that is not specifically admitted. Tempus responds to each paragraph in the Complaint as follows:

RESPONSE TO ALLEGATIONS CONCERNING OVERVIEW OF THE ACTION

1. Tempus admits that Guardant's Complaint purports to state an action for declaratory relief under 28 U.S.C. § 2201 and Rules 8 and 57 of the Federal Rules of Civil Procedure. Tempus admits it sent a cease-and-desist letter to Guardant on January 13, 2025, about Guardant's false and misleading advertisements comparing Guardant's liquid biopsy assay, Guardant360, and Tempus's assay, Tempus xF+. Tempus denies all remaining allegations in Paragraph 1 of the Complaint.

RESPONSE TO ALLEGATIONS CONCERNING THE PARTIES

2. Tempus admits the allegations in Paragraph 2 of the Complaint.

3. Tempus admits the allegations in Paragraph 3 of the Complaint.

RESPONSE TO ALLEGATIONS CONCERNING JURISDICTION AND VENUE

4. Tempus admits that this Court has original jurisdiction over this case under 28 U.S.C. § 2201 and 28 U.S.C. § 1331.

5. Tempus admits that venue is proper in this Court.

6. Tempus admits that this Court is authorized to grant declaratory judgment under the Declaratory Judgment Act, 28 U.S.C. § 2201.

7. Tempus admits that it is a Delaware corporation and is subject to personal jurisdiction. Tempus denies all remaining allegations in Paragraph 7 of the Complaint.

8. Tempus admits that it is subject to personal jurisdiction. Tempus denies all remaining allegations in Paragraph 8 of the Complaint.

RESPONSE TO ALLEGATIONS CONCERNING THE PARTIES' DISPUTE

9. Tempus is without knowledge sufficient to admit or deny the allegations of Paragraph 9 of the Complaint and, therefore, denies them.

10. Tempus admits that a liquid biopsy is a sampling and analysis of non-solid biological tissues, such as a patient's blood. Tempus admits a liquid biopsy is distinct from a solid-tumor biopsy. Tempus admits that the DNA in the cells making up an organ or tissue may contain biomarkers that indicate the presence of disease. Tempus denies all remaining allegations in Paragraph 10 of the Complaint.

11. Tempus admits that DNA originating from cells in different organs and tissues circulates in the human bloodstream and is known as "cell-free DNA" or "cfDNA." Tempus admits that a blood draw can capture cell-free DNA. Tempus admits that cell-free DNA can be analyzed for relevant biomarkers indicating the presence of disease. Tempus denies all remaining allegations in Paragraph 11 of the Complaint.

12. Tempus is without knowledge sufficient to admit or deny the allegations of Paragraph 12 of the Complaint and, therefore, denies them.

13. Tempus is without knowledge sufficient to admit or deny the allegations of Paragraph 13 of the Complaint and, therefore, denies them.

14. Tempus is without knowledge sufficient to admit or deny the allegations of Paragraph 14 of the Complaint and, therefore, denies them.

15. Tempus admits that liquid biopsies can often generate results faster than solid-tumor biopsies. Tempus admits cfDNA samples may allow for the detection of mutations that may be missed by a tissue biopsy sample. Tempus is without knowledge sufficient to admit or deny the remaining allegations in Paragraph 15 of the Complaint and, therefore, denies them.

16. Tempus denies that all of Guardant's patents were validly issued or are novel and/or useful. Tempus is without knowledge sufficient to admit or deny the remaining allegations of Paragraph 15 of the Complaint and, therefore, denies them.

17. Tempus admits it was founded in 2015 and was formerly known as Tempus Labs, Inc. Tempus denies that it has capitalized on any of Guardant's efforts to develop any liquid biopsy tests. Tempus denies all remaining allegations in Paragraph 17 of the Complaint.

18. Tempus admits it makes liquid biopsy panels that compete with Guardant's products. Tempus denies all remaining allegations in Paragraph 18 of the Complaint.

19. Tempus admits it sells a liquid biopsy panel known as Tempus xF+. Tempus denies all remaining allegations in Paragraph 19 of the Complaint.

20. Tempus admits that Guardant developed an advertising campaign purporting to reflect the performance of Guardant's and Tempus's assays, which was intended to and did falsely claim or imply that Tempus xF+ is inferior to Guardant360. Tempus denies that the xF+ is inferior to Guardant360. Tempus denies the remaining allegations in Paragraph 20 of the Complaint.

21. Tempus admits that on January 13, 2025, its Executive Vice President and General Counsel, Andy Polovin, sent a letter to John Saia, Guardant's Chief Legal Officer. Tempus admits Mr. Polovin's letter alleged Guardant's advertising comparing Guardant360 with Tempus xF+ was false and misleading. Tempus denies all remaining allegations contained in Paragraph 21 of the Complaint.

22. Tempus denies that the claims in its letter are erroneous. Tempus is without knowledge sufficient to admit or deny the remaining allegations of Paragraph 22 of the Complaint and, therefore, denies them.

RESPONSE TO GUARDANT'S FIRST COUNT (DECLARATORY RELIEF)

23. Tempus repeats its answers to the allegations above as if fully set forth herein.

24. Paragraph 24 states a legal conclusion to which no response is required, and Tempus denies any allegations therein.

25. Tempus admits it alleges that Guardant's advertising comparing its Guardant360 product to Tempus's xF+ product is false and misleading. Tempus denies all remaining allegations contained in Paragraph 25 of the Complaint.

26. Tempus admits that an actual controversy exists between Guardant and Tempus regarding the rights, duties, and obligations of Guardant, including regarding Guardant's comparisons of Guardant 360 to Tempus's xF+ product. Tempus denies all remaining allegations in Paragraph 26 of the Complaint.

27. Tempus admits that an actual controversy exists between Guardant and Tempus regarding the rights, duties, and obligations of Guardant, including regarding Guardant's comparisons of Guardant 360 to Tempus's xF+ product. The remaining allegations in Paragraph 27 state legal conclusions to which no response is required, and Tempus denies any allegations therein.

RESPONSE TO GUARDANT'S PRAYER FOR RELIEF

Tempus denies that Guardant is entitled to any of the relief requested in the Complaint or otherwise.

AFFIRMATIVE DEFENSES

Subject to its responses above, and upon information and belief, Tempus alleges and asserts the following defenses in response to the allegations of the Complaint. Regardless of how Tempus lists each defense (whether affirmative or not), Tempus undertakes the burden of proof only as to those defenses that are deemed affirmative defenses as a matter of law. Additional defenses may be uncovered during discovery and Tempus reserves all rights to amend, modify, revise, or supplement its Answer and/or plead additional affirmative defenses.

FIRST AFFIRMATIVE DEFENSE

The Complaint, in whole or in part, fails to state a claim against Tempus upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

Guardant's claims are barred because Guardant has suffered no harm or damages.

THIRD AFFIRMATIVE DEFENSE

Guardant's claims are barred because Tempus was not the legal or proximate cause of Guardant's injuries, to the extent that Guardant suffered any injuries.

FOURTH AFFIRMATIVE DEFENSE

Guardant's claims are barred because Guardant lacks standing to sue.

FIFTH AFFIRMATIVE DEFENSE

Guardant's claims are barred by the doctrine of unclean hands.

SIXTH AFFIRMATIVE DEFENSE

Guardant's claims are barred by the doctrine of estoppel.

SEVENTH AFFIRMATIVE DEFENSE

Guardant's claims are barred because Guardant failed to mitigate its damages, to the extent that Guardant has suffered any damages.

EIGHTH AFFIRMATIVE DEFENSE

Guardant's claims are barred because Guardant's alleged injuries and damages, if any, were proximately caused by Guardant's own actions, inactions, and/or omissions.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Tempus respectfully demands a trial by jury on all issues so triable.

Dated: March 14, 2025

Respectfully submitted:

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 14, 2025, a copy of the foregoing document was served on the counsel listed below in the manner indicated:

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